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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,399	08/16/2001	Guru V. Betageri	WESTU1.001A	3889

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 01/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,399

Applicant(s)

Betageri

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10-30-02
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The requests for the extension of time and reconsideration filed on 10-30-02 are acknowledged.

Claims included in the prosecution are 1-38.

Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2. Claims 8, 13-23 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

In claims 8, 13 and 35 applicant recites the terms, 'liquids' and 'suspensions'. The distinction is unclear. If applicant's intent is to convey a single phase composition by the term, 'liquid' it is unclear how this is possible since phospholipids are lipophilic and will only form a suspensions. Applicant's arguments have been fully considered, but are not found to be persuasive since the examiner was not questioning the formation of liquids in instant invention. The issue here is the difference between the liquids and suspensions. Even enterically coated formulations will be in a suspension form since the amphiphilic

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phospholipid is present in the formulation and enteric formulations are designed to dissolve only in the lower intestinal tract.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-12 and 37-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-

would
cancel

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39 and 41-60 of copending Application No. 09/562,207. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to the phospholipid preparations and methods and although instant claims recite the term non-liposomal preparations', instant specification refers to them as 'proliposomal preparations' same as that used in the claims of said copending application. .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant appear to argue that the claims in instant application recite non-liposomal forms whereas the claims in the copending application are directed to proliposomal preparations. This argument is not found to be persuasive since as pointed out in the prior art rejections, although instant claims recite 'non-liposomal preparations', in the specification these are referred to as 'proliposomal preparations'. This shows the intent of applicant to include proliposomal preparations in the definition of 'non-liposomal preparations'. The rejection is maintained.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Desai (5,206,219).**

Desai discloses enteric formulations containing an active agent and a phospholipid and methods of making the preparation in the form of either capsules or tablets. The active agents include hormones, enzymes, interferon and cyclosporin. The phospholipids taught are DMPC and egg lecithin (note the abstract, col. 2, lines 54-62; col. 5, line 56 through col. 6, line 17; Examples and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Desai merely discloses formulating a pre-emulsion solution consisting of a polyol solvent and a lipid solvent which can be encapsulated in a gelatin capsule and that Desai does not teach or suggest a non-liposomal pharmaceutical composition comprising at least one pharmaceutically active agent, at least one phospholipid and an enteric coating surrounding the pharmaceutically active agent and phospholipid. These arguments are not found to be persuasive for the following reasons. First of all, instant claim language 'non-liposomal pharmaceutical formulation' includes any form of formulation other than liposomes. Secondly, instant claim language does not does not exclude the presence of a capsule over the phospholipid and the active agent which is then enterically coated. Since Desai teaches an enteric coating of the capsules containing

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the phospholipid, the enteric coated is construed as present over the phospholipid and the active agent. Desai meets the requirements of instant claims.

Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 8. Claims 1-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakagame (4,615,885) in view of Ganter (5,635,206) by themselves or in combination.**

Nagakame discloses a method of preparation of lyophilized powders containing a phospholipid and the active agent and coating them with an enteric coating and the formulations are either in the form of tablets or capsules. The method of preparation of the powders involves dissolving the phospholipid and evaporating the organic solvent. Since the active agent is hydrophilic, an aqueous medium containing the active agent is added and the resultant mixture is lyophilized to prepare proliposomal powders (which upon contact with water form liposomes just as in instant case). Nagakame's process thus, involves an additional step of adding the aqueous medium.

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Ganter while disclosing proliposomal compositions teaches that a mixture suitable for the preparation of liposomes can be made by mixing lecithin (phospholipid), solubilizer and/or lipophilic and hydrophilic active agents and preparing a dry powders without the addition of water (note the abstract, col. 2, lines 4-59, examples and claims).

Omitting the step of the addition of an aqueous solution the dried phospholipid in Nagakame and prepare the dry powders would have been obvious to one of ordinary skill in the art since Ganter teaches that phospholipid mixtures could be prepared without the addition of water and still get liposomal preparations when the dry powders come into contact with water. It should be noted that although instant claims recite 'non-liposomal preparations', in the specification these are referred to as 'proliposomal preparations'.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant appear to argue that Nakagami's preparations are liposomes. This argument is not found to be persuasive since Nakagami teaches powdered preparations meaning that the formulations will only be in a liposomal form with subsequent addition of water; as noted above, although instant claims recite 'non-liposomal preparations', in the specification these are referred to as 'proliposomal preparations'.

Applicant's arguments with regard to Ganter are not found to be persuasive. Applicant appear to argue that Ganter's proliposomes contain significant amounts of water. This argument is not found to be persuasive since instant claims do not exclude the solubilizer. With regard to applicant's arguments that Ganter fails to teach or suggest

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preparation of a 'dry powder', the examiner points out that instant claims merely recite 'non-liposomal formulations' and do not require the formulations in a dry powder form. Applicant's arguments that Nakagami teaches away from omitting the step of the addition of water because forming the urokinase-carrying liposome is integral to the invention are not found to be persuasive since it is well-known in the art that proliposomes can be formed without the addition of water; liposomes are formed only after the addition of water to the phospholipid powder. EP 0087993 is cited of interest in this regard. This reference shows that spray dried powders of phospholipids (prepared without the use of water) form liposomes upon the addition of water.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

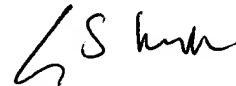
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

January 7, 2003